

REMARKS/ARGUMENTS

In response to the final Office Action dated November 17, 2008, Applicants submit herewith a terminal disclaimer and the remarks hereinbelow. Withdrawal of the nonstatutory obviousness-type double patenting rejection and reconsideration and withdrawal of the obviousness rejection are respectfully requested.

Claims 12-24 and 26 remain rejected on the ground of nonstatutory obviousness-type double patenting as allegedly unpatentable over claims 1-9 of U.S. Patent No. 6,432,445 in view of U.S. Pat. No. 5,962,019. The same claims remain rejected on the same ground as allegedly unpatentable over claims 1-14 of U.S. Patent No. 6,767,555 in view of U.S. Patent No. 5,962,019. In response thereto, submitted herewith is a terminal disclaimer disclaiming that portion of term of any patent issuing from the above-identified application, which would extend past the term of the first to expire of U.S. Patent Nos. 6,432,445 and 6,767,555. Withdrawal of the double patenting rejection is therefore respectfully requested.

Claims 12-24 and 26 remain rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Pat. No. 5,342,625 to Hauer et al. in view of U.S. Pat. No. 5,962,019 to Cho et al. Hauer et al. has been cited for allegedly teaching cyclosporin pharmaceutical compositions in the form of micro-emulsion pre-concentrates that are filled in hard gelatin capsules. The formulations include a surfactant such as Cremophor RH 40, described as a reaction product of hydrogenated or natural vegetable oil and ethylene glycol. Hauer et al. has also been cited for teaching compositions comprising propylene glycol and ethanol, preconcentrate compositions free of water and which form spontaneous emulsions. The Examiner admits that Hauer et al. fail to teach polyethylene glycol in combination with the lower alkanols. Cho has been cited for teaching that polyethylene glycol co-solvents absorb water molecules, which may be present in the formulations, and also impart desirable properties such as viscosity, stability, etc.

It is respectfully submitted that Cho et al. also teach at column 3, lines 62-64: "Also present in the orally acceptable vehicle will be at least one non-ionic

polyoxyalkylene surfactant, usually not more than two non-ionic polyoxyalkylene surfactants." Examples of such non-ionic polyoxyalkylene surfactants include polyoxyethylene (4) lauryl ether (BRIJ 30[®]) and polyoxyethylene (2) mono sorbitan molo-oleate (TWEEN 80[®]). See '019 patent, column 4, lines 14-16. In contrast, as presently amended, claims 12-24 and 26 do not include such a non-ionic polyoxyalkylene surfactant.

It was argued previously by Applicants that in formulating a rejection under 35 U.S.C. § 103(a), based upon a combination of prior art elements, it remains necessary to identify the reasons why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. *KSR International v. Teleflex, Inc.*, 82 USPQ 2d 1385 (U.S. 2007). Following *KSR* in the instant case, it remains necessary to identify the reasons why a person of ordinary skill in the art would have chosen to include polyethylene glycol taught by Cho et al., and also would have chosen to omit a non-ionic polyoxyalkylene surfactant, *when Cho et al. specifically teaches such non-ionic polyoxyalkylene surfactant as an essential element*.

On page 8 of the November 17, 2008 final office action, under "Response to Argument", the Examiner indicates that Applicants arguments are not persuasive because "Hauer clearly emphasizes the need for minor amounts of water in col. 5, L 54-63, and Cho teaches that polyethylene glycol for the advantage of absorbing water molecules that may be present in the composition thereby reducing the possibility for precipitation of the cyclosporine and also impart the desired viscosity and stability. Therefore, a skilled artisan preparing microemulsions without or minimum amounts of water would have looked at the teachings of Cho, also directed to cyclosporine compositions where excess water is absorbed to impart stability. Hence the rejection has been maintained."

Applicants respectfully submit that the Examiner has not addressed the argument previously submitted, that Cho et al. specifically teaches a non-ionic polyoxyalkylene surfactant as an essential element. Nor has the Examiner addressed the arguments previously set forth that in formulating a rejection under 35 U.S.C. § 103(a), based upon a combination of prior art elements, it remains necessary to identify the reasons why a person of ordinary skill in the art would have combined the prior art elements in the

manner claimed. *KSR International v. Teleflex, Inc.*, 82 USPQ 2d 1385 (U.S. 2007). Following *KSR* in the instant case, it remains necessary to identify the reasons why a person of ordinary skill in the art would have chosen to include polyethylene glycol taught by Cho et al., and also chosen to *omit* a non-ionic polyoxyalkylene surfactant, *when Cho et al. specifically teaches such non-ionic polyoxyalkylene surfactant as an essential element.*

The elements and features of Applicants' claims cannot reasonably be said to be present in the asserted combination of references. The failure of an asserted combination to teach or suggest each and every feature of a claim remains fatal to an obviousness rejection under 35 U.S.C. § 103, despite any recent revision to the Manual of Patent Examining Procedure (MPEP). Section 2143.03 of the MPEP requires the "consideration" of every claim feature in an obviousness determination. To render the instant claims unpatentable, however, the Office must do more than merely "consider" each and every feature for the claims. Instead, the asserted combination must also teach or suggest each and every claim feature. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974) (emphasis added) (to establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art). Indeed, as the Board of Patent Appeal and Interferences has recently confirmed that a proper obviousness determination requires that the Office make "a searching comparison of the claimed invention - *including all its limitations* - with the teaching of the prior art." See *In re Wada and Murphy*, Appeal 2007-3733, citing *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis in original).

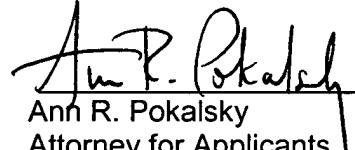
Further, the necessary presence of all claim features is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including ascertaining the differences between the claimed invention and the prior art. *Graham*, 383 U.S. 1 (1966). Applicants submit that this is why Section 904 of the MPEP instructs examiners to conduct an art search that covers "the invention as *described and claimed*." (emphasis added). Lastly, Applicant respectfully directs attention to MPEP § 2143, the instructions of which buttress the conclusion that obviousness requires at least a suggestion of all of the features of a claim, since the Supreme Court in *KSR Int'l v. Teleflex Inc.* stated that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of

obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

In sum, it remains well-settled law that obviousness requires at least a suggestion of all of the features in a claim. *See In re Wada and Murphy, citing CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (stating "obviousness requires a suggestion of all limitations in a claim.") and *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Based on the evidence as a whole, the combination of references cited by the Office does not support a finding of *prima facie* obvious. *See* MPEP § 2144.08; *In re Bell*, 991 F.2d 781, 784 (Fed. Cir. 1993); *In re Kulling*, 897 F.2d 1147, 1149 (Fed. Cir. 1990)). The Office has not shown a suggestion or motivation to modify the citations or combine the citations teachings to arrive at Applicants' claims. In the present application, the results of the factual inquiries under *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1, 17-18 (1966) do not support that the pending claims are *prima facie* obvious under 35 U.S.C. §103(a). Withdrawal of the rejection of claims 12-24 and 26 under 35 U.S.C. §103(a) is therefore warranted.

Accordingly, in view of the foregoing remarks and amendments, it is respectfully submitted that the present claims are in condition for allowance, which action is earnestly solicited.

Respectfully submitted,


Ann R. Pokalsky
Attorney for Applicants
Reg. No. 34,697

Dilworth & Barrese, LLP
1000 Woodbury Road, Suite 405
Woodbury, New York 11797

(516) 228-8484